

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA, *et al.*,
ex rel. Lauren Kieff,

Plaintiffs,

v.

WYETH,

Defendant.

Case No. 03-CV-12366

Hon. Douglas P. Woodlock

UNITED STATES OF AMERICA, *ex rel.*
William LaCorte,

Plaintiffs,

v.

WYETH,

Defendant.

Case No. 06-CV-11724

Hon. Douglas P. Woodlock

PROPOSED CONFIDENTIALITY AGREEMENT AND PROTECTIVE ORDER

The parties, by their undersigned Counsel, hereby agree pursuant to Federal Rules of Civil Procedure 26 and 34, subject to approval and entry by the Court, as follows:

1. This Order shall govern all information produced in response to a discovery request, whether formal or informal, in or related to the above-captioned litigation.

2. **Definition of Confidential Information.** The designation “Confidential” shall be limited to information that any producing party, including any third party, in good faith, believes to contain:

a. Pricing data governed by the confidentiality provisions of the Social Security Act, 42 U.S.C. § 1396r-8(b)(3)(D), or any applicable state law;

b. “Confidential Health Information.” For the purposes of this protective order,

“Confidential Health Information” shall mean any document or information supplied in any form, or any portion thereof, that identifies an individual in any manner and related

to the past, present, or future care, services, or supplies relating to the physical or mental health or condition of such individual, the provision of health care to such individual, or the past, present, or future payment for the provision of health care to such individual.

“Confidential Health Information” specifically includes “protected health information” and “individually identifiable health information” as such terms are defined by the Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. Part 160, promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996. “Confidential Health Information” includes, but is not limited to, medical bills, claims forms, charge sheets, medical records, medical charts, test results, notes, dictation, invoices, itemized billing statements, remittance advice forms, explanations of benefits, checks, notices, and requests. “Confidential Health Information” also includes all notes, summaries, compilations, extracts, abstracts, or oral communications that contain, are based on, or are derived from “Confidential Health Information.”

“Confidential Health Information” also includes material subject to the provisions of the Privacy Act, 5 U.S.C. § 552a, or to the provisions of 45 C.F.R. Part 164. “Confidential Health Information” also includes any materials covered by the privacy laws of any individual states as applicable. In order to facilitate the production of “Confidential Health Information”, the parties may produce “Confidential Health Information” to any party in the litigation captioned *United States of America, et al., ex rel. Lauren Kieff v. Wyeth*, or the litigation captioned *United States of America, ex rel., William LaCorte v. Wyeth*, in unredacted form without such production constituting a waiver of confidentiality.

- c. Proprietary or commercially sensitive information less than five years old which constitutes a trade secret under state or federal law.

3. **Designation of Confidential Information.** The designation of information as Confidential shall be performed in the following manner:

- a. A Party or Third Party may designate information provided as Confidential by placing on or affixing to a document containing protected information the phrase “CONFIDENTIAL” on each page of the document entitled to such designation (in such manner as will not interfere with the legibility thereof). Information designated by a party as Confidential prior to September 1, 2010, shall not be treated as Confidential under the terms of this Order unless the party specifically re-designates that information as Confidential after the party signs this Order.
- b. If information cannot practically be designated Confidential for whatever reason including, but not limited to, the format of the electronically stored information, the producing party shall provide written notice of the designation of the information to the receiving party.
- c. Interrogatory answers or other responses to written discovery and information contained therein shall be designated as Confidential by means of a statement at the conclusion of each answer specifying the information that is Confidential contained therein, or by another method that clearly indicates which portion of the answer or information is considered Confidential, and by placing the legend referenced in subpart (a) above on the front of any set of interrogatory answers containing such information.
- d. A designation that information is Confidential shall constitute a representation to the Court, made in good faith, that counsel believes that the information so designated constitutes Confidential information as defined in this Order.
- e. If a producing party inadvertently or unintentionally produces to a receiving party any Confidential information without designating it as protected pursuant to paragraph 3(a),

3(b) or 3(c), the producing party shall promptly give notice to the receiving party in writing and thereafter the receiving party shall treat the information as Confidential information. Such inadvertent or unintentional disclosure shall not be deemed a waiver in whole or in part of the producing party's claim of restriction either as to specific documents and information disclosed or on the same or related subject matter.

4. **Right to Challenge Designation.** Nothing in this Order shall be construed in any way as a finding that information designated Confidential actually is Confidential information. If a party to this Order disagrees, in full or in part, with a producing party's designation of Confidential information, such party may notify the producing party in writing stating the basis for its disagreement, and the parties shall confer in good faith as to the designation of the Confidential information. If the parties are unable to reach agreement on the proper designation of the Confidential information, either party may move to re-classify Confidential information pursuant to the terms of this Order.

5. **Access to Confidential Information.** Information designated Confidential may be disclosed only to the following persons:

- a. The Court;
- b. The parties' counsel and in-house counsel directly managing the litigation;
- c. Experts or consultants retained by the parties;
- d. Stenographic and video reporters engaged in proceedings incident to this matter;
- e. Discovery consultants, processors and vendors, outside document copying services, document coding or computerization services, demonstrative exhibit vendors and jury consultants;
- f. Associated personnel of any person within categories (a) through (e) for whom access to

Confidential information is necessary to assist such persons in the action, including any Court personnel assisting the Court, litigation assistants, paralegals, secretarial or other clerical personnel, stenographers or other persons involved in taking or transcribing testimony in this action, and principals and employees of the firm with which consultants or experts are associated;

- g. Any person known to have created or received Confidential information outside of discovery;
- h. During depositions and preparation for depositions, any deponent;
- i. Law enforcement personnel, including United States Department of Justice Attorneys, United States Attorneys, Plaintiff States' Attorney General Offices, their authorized subordinates, and contractors engaged in the purposes of assisting the same with this matter; and
- j. Any private mediators utilized in this matter.

6. **Limitations.** Nothing contained in this Order shall abrogate any legal obligation of any party to disclose upon appropriate request to any state, any agency or department of the United States, or any division of any such agency or department, Confidential information relating to any potential violation of law or regulation, or relating to any matter within that agency's jurisdiction, nor shall anything contained in this Order abrogate any legal right to use any such Confidential information by a federal agency in any proceeding relating to any potential violation of law or regulation, or relating to any matter within that agency's jurisdiction. Nor shall anything contained in this Order abrogate any legal obligation of any party to disclose any document or information as required by law, or to Congress pursuant to a Congressional request.

7. **Transcripts.** During any deposition in which Confidential information is discussed, counsel for any party or third party may: (a) designate, on the record, the portions of the transcript

that will contain Confidential information, in which case the portions of the deposition so designated on the record shall be treated as Confidential information, respectively, and placed in a separately bound volume; or (b) designate in writing to counsel for all parties, within fourteen (14) days of the transcript's delivery, the transcript portions which are to be treated as Confidential information. All deposition transcripts will be considered as Confidential information until the notice set forth above or until the expiration of fourteen (14) days from the transcript's delivery.

8. **Filing Under Seal.** A party seeking to file another party's Confidential discovery material shall provide the producing party notice of the Confidential discovery material it intends to use at least two (2) days prior to filing. The producing party shall then have two (2) days in which either to consent to the request to file said information in the public record or to file a motion pursuant to Local Rule 7.2 to keep such papers under seal. If the producing party moves to keep papers under seal, the papers with the designated Confidential information under seal, or with any references to the Confidential information, will be filed under seal or redacted, as appropriate, until the Court rules on the motion to seal.

9. **Modification Permitted.** Nothing in this Order shall prevent any party from seeking modification of this Order or from objecting to discovery that it believes to be otherwise improper.

10. **Inadvertent or Mistaken Productions Shall Not Waive Privilege or Protection.** If information subject to a claim of attorney-client privilege or work product protection or any other privilege or protection is inadvertently or mistakenly produced, such production shall in no way prejudice or otherwise constitute a waiver of, or estoppel as to, any claim of privilege or protection for such information as provided under applicable law, including Federal Rule of Evidence 502. If a producing party has inadvertently or mistakenly produced information subject to a claim of protection or privilege, and if the producing party makes a written request for the return of such information, the information for which a claim of inadvertent production is made (including any

analyses, memoranda or notes which were internally generated based upon such inadvertently-produced information), as well as all copies, shall be either destroyed or returned immediately to the producing party, even if the receiving party disputes the claim of privilege. If the receiving party disputes the producing party's assertion of privilege, the producing party must submit the potentially privileged information to the Court for review *in camera*.

11. **Miscellaneous.**

- a. Nothing in this Order shall prevent a party from any use of its own Confidential information.
- b. The parties may agree to waive any provision of this Order, provided such waiver is made in writing.
- c. Proper notice under this Order, when required, shall be effected by letter or email.

12. **Counterparts.** This Order may be signed in counterpart, and each such counterpart shall be deemed an original.

13. **Entire Agreement.** This Order constitutes the entire agreement of the parties and supersedes all prior communications, understandings and agreements relating to the subject matter hereof, whether oral or written.

AGREED TO BY:

For Defendant Wyeth:

/s/ Colleen A. Conry

Counsel for Defendant Wyeth

For Plaintiff United States:

/s/ Gregg D. Shapiro

Assistant United States Attorney



APPROVED AND SO ORDERED this

10th day of January, 2011.

BY THE COURT:

Douglas P. Woodlock

Hon. Douglas P. Woodlock
United States District Judge